DEPARTMENT OF HEALTH & HUMAN SERVICES

D1355B
Food and Drug Administration
San Francisco District

1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: (510) 337-6700
FAX: (510) 337-6702

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 31, 1997

Facility ID #: 190991
FDA Reference #: 2952140

Ms. Theresa DeSantos
Owner/Operator
Mobile Mammography Service
6314 Houston Avenue
Hanford, CA 93230

WARNING LETTER

Dear Ms. DeSantos:

We have established that your facility was conducting breast cancer screening or diagnosis through mammography activities and that your facility is not certified by the Food and Drug Administration (FDA) as required by the Mammography Quality Standards Act of 1992 (MQSA). This is a consequence of the fact that your facility is not accredited by an approved accreditation body nor has your facility submitted an acceptable application to an approved accreditation body, as is required by the MQSA as a prerequisite to certification.

Your facility was investigated on August 26, 1997, by John A. Gonzalez, Investigator for the U.S. Food and Drug Administration and again on December 19, 1997 by John M. Doucette, MQSA Inspector for the U.S. Food and Drug Administration. This investigation revealed that your facility failed to comply with the requirements for certification, as specified in Title 21, Code of Federal Regulations (CFR), Part 900.11, as follows:

> During the period of June 11, 1997 to August 26, 1997, your facility was performing mammography without obtaining accreditation from an approved accreditation body, such as the American College of Radiology (ACR), and certification from the Food and Drug Administration (FDA).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the MQSA and regulations under the Act.

You are advised that performing mammography without a certificate issued by the FDA is unlawful under the MQSA. If your facility does not stop performing mammography immediately, it may be subject to civil money penalties up to $10,000 for failure to obtain a certificate (42 U.S.C. 263b(h)(2)(A)). Continued operation of a facility without a certificate may also result in injunction.

Before your facility can lawfully resume mammography, you must notify the appropriate accreditation body (in the case of your facility, the accreditation body is the American College of Radiology (ACR)), obtain the appropriate materials and forms for applying for accreditation, and submit the required information to the accreditation body. Once the accreditation body notifies FDA that your facility has met their requirements to begin the accreditation process, FDA will issue your facility a provisional certificate.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you will take to either apply to an approved accreditation body or to permanently discontinue mammography. Continuing to perform mammography without a certificate may result in regulatory action being initiated by the Food and Drug Administration without further notice.

Your response should be sent to:

Mr. John M. Doucette
MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

If you have any questions, please contact John Doucette at (510) 337-6793.

Sincerely yours,

Charles D Moss
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District

cc: Trisha Edgerton, Chief, Mammography Accreditation
California Department of Health Services
Radiological Health Branch
P.O. Box 942732
601 N. 7th Street, MS-178
Sacramento, CA 94234-7320